After Final Office Action of February 20, 2007

## **REMARKS**

Docket No.: 0106586.00185US1

This Amendment is filed in response to the Office Action issued February 20, 2007. Claims 1-38 are pending and have been rejected by the Office Action. Independent claims 1 and 20 are currently amended. New claims 39-42 have been added by this amendment. No new matter is believed to have been added.

The Office Action rejected claim 1 and 20 under 35 U.S.C. § 112 on the basis that essential structure, i.e., a scaffold which attaches the center joint to the cylindrical member had been omitted. With regard to the 35 U.S.C. § 112 rejection, Applicants have given the Examiner's suggestion full consideration, but Applicants note that in some embodiments, a scaffold may not be provided and is not required, *see*, *e.g.*, Fig. 35 and Specification, para. [0107]. The center joint can be held in place, for example, by clamping forces exerted inside the ends of the split portion of the cylindrical member. In some embodiments, a tissue scaffold is also provided. Dependent claims 17 and 18, and newly added independent claim 42, for example, recite the presence of a tissue scaffold. Accordingly, claims 1 and 20 are believed to claim the invention appropriately, without the suggested amendment.

The Office Action rejected pending claims 1-10, 12, 15-23, 26-32 and 34-38 were rejected under 35 U.S.C. § 103 over Sideris (US 5284488) in view of Huebsch (US 5853422). Applicants respectfully traverse the 35 U.S.C. § 103 rejection. These remarks are directed primarily to Claim 1 by way of illustration. The Office Action asserted that Sideris teaches, in part, an anchor member having an elongate oval shape, a retrieval mechanism and particularly one that reduces the profile of the device such that the device may be drawn into a catheter and aligns said first and second anchor members in a longitudinal orientation. The Office Action asserted that Huebsch teaches an anchor member comprising a generally cylindrical member split along a central portion of its length to form an elongate oval. The Office Action further asserted that it would have been an obvious matter of design choice to form the anchor members from generally cylindrical members split along the center portion of their length to form an elongate oval. Claim 1 recites "wherein at least one anchor member of at least one of said first and second sides comprises a generally cylindrical member, having a longitudinal axis, split along the central portion of its length to form an elongate oval, wherein the center joint is attached to at least one of the generally cylindrical members such that the longitudinal axis of the

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anchor member extends generally transverse to the center joint in the deployed configuration."

This configuration is not obvious in view of the prior art.

Applicants first address the structure of the anchor member. As noted in the November 21, 2006 Response, Huebsch refers to a "cylindrical shaft 12" the provides almost the entire device as configured in the delivery catheter and not specifically an anchor member. Anchoring in Huebsch is provided by the "struts 22" bending in a radially outward manner and attached at their ends to a "central portion 18", wherein the respective portions of the cylindrical shaft 12 and struts 22 are parallel, and further, coaxial, to an axis of the device that extends through the defect. In contrast, the presently claimed generally cylindrical member is oriented and attached to the center joint in such a way that the a longitudinal axis of the cylindrical member extends generally transverse to the center joint in the deployed configuration, as is further claimed. Accordingly, the usage, orientation, operative mechanical forces and configuration of the presently claimed cylindrical anchor member and overall device is different from Huebsch. Such a configuration is not taught in Huebsch, nor would it be obvious to modify Huebsch to form the presently claimed anchor member because the overall configuration of Huebsch would have to be completely changed. Accordingly the prior art does not show or suggest the presently claimed anchor member. Accordingly the combination of Huebsch and Sideris is not believed to teach the presently claimed invention.

The Office Action asserts that "it would have been an obvious matter of design choice to form the anchor members from generally cylindrical members split along the center portion of their length, since Applicant has not disclosed that such a configuration provides any advantage over the configuration of Sideris, and it appears the anchor members perform the task of increasing the size and surface area of the anchor member, thereby improving dislodgement resistance of the closure device equally well as that disclosed in the application." Applicants respectfully disagree. Far from being an obvious matter of design choice, the novel construction of the at least one cylindrical anchor member in the presently claimed configuration provides a device that, at the very least, offers ease of retrieval. At least one retrieval mechanism is described in detail in the specification at para. [0012]. Although the Office Action asserts that Sideris shows a retrieval mechanism, Sideris does not in fact describe a retrieval mechanism. The mere provision of "nylon safety thread 44" for *deployment*, does not itself teach a *retrieval* 

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mechanism. There is no teaching in Sideris to determine, for example, how the disks 34, 38 would be properly oriented in order to be retrieved into the catheter. This is one example of why the presently claimed anchor member is not merely an obvious design variation. Accordingly, the presently claimed invention is not believed to be obvious in view of the prior art for this further reason. Claims 1 and 20, which contains limitations analogous to claim 1, are believed to be allowable over the cited prior art.

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New claims 39-41, which depend from claim 1, and new claim 42, which is independent, have been added to further claim aspects of the invention.

Claims 2-10, 12, 15-19, 21-23, 26-32 and 34-38 were also rejected under 35 U.S.C. 103 over the combination of Sideris and Huebsch. The claims are allowable at least because they depend from an allowable base claim.

Claims 13 and 33 were rejected under 35 U.S.C. 103 over the combination of Sideris and Huebsch further in view of Hannam (US 5649959). Hannam does not address the deficiencies noted above of Huebsch and Sideris with respect to claims 1 and 20, from which claims 13 and 33, respectively, depend. Claims 13 and 33 are allowable at least because they depend from claims 1 and 20, respectively, and include the novel features recited with respect thereto

Claims 11 and 14 were rejected under 35 U.S.C. 103 over the combination of Sideris and Huebsch further in view of Kanesake (US 5776183). Kanesake does not address the deficiencies noted above of Huebsch and Sideris with respect to claim 1, from which claims 11 and 14 depend. Claims 11 and 14 are allowable at least because they depend from claim 1 and include the novel features recited with respect thereto.

Claims 24-26 were rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sideris and Huebsch further in view of Simon (US 5741297). Simon does not address the deficiencies noted above of Huebsch and Sideris with respect to claim 20, from which claims 24-26 depend. Claims 24-26 are allowable at least because they depend from claim 20 and include the novel features recited with respect thereto.

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In view of the above remarks, Applicants believe that the pending application is in condition for allowance. Applicants have enclosed instructions to charge the appropriate fees for the Request for Continued Examination and the additional claims. No additional fees are believed to be due in connection with this response. However, please charge any fees due in connection with this application or credit any overpayments to Deposit Acct. No. 08-0219.

Respectfully submitted,

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